

Structured Product Labeling (SPL) OTC Sub-team Teleconference

June 1, 2009, 1:00 – 2:00 pm ET

Call Summary

I. Call Attendees (based on emails received)

Attendance is based on email replies received. Call participants who are not listed below but were on the call (or if you are listed and were not on the call) should notify Marcia Howard.

-  David Brown, Colgate-Palmolive
-  Sue Crain, Watson Co.
-  Shelia Dy Juanco, Medline Industries, Inc.
-  Mary Beth Fritz, Prestige Brands Holdings, Inc.
-  David Grob, Chattem, Inc.
-  Michele Hewitt, Sandoz Inc, Broomfield
-  Juris Lazdins, Novartis Consumer Health, Inc.
-  Carolyn Lindsay, Cardinal Health
-  Paula Markert, GlaxoSmithKline Consumer Healthcare (sub-team co-leader)
-  Devon Morgan, Perrigo Company (sub-team co-leader)
-  Janet Riffitts, McNeil Consumer Healthcare
-  Eva Rivera, Glemser Technologies Corporation
-  Ranga Velagaleti, BASF, Inc.
-  Gary Saner, Reed Technology and Information Services, Inc.
-  David Schilling, Chattem, Inc.
-  Howard Shatz, Data Conversion Laboratories, Inc.
-  Carl Strotz, Wyeth Consumer Healthcare
-  Beth Thompson, Medline Industries, Inc.
-  Craig Trautman, Intagras

 Barbara Wolfe, Wyeth Consumer Healthcare

 Marcia Howard, CHPA staff (sub-team liaison)

II. Next Standing Teleconference: June 15, 2009

III. FDA [Guidance for Industry](#) - Final

The final guidance was released on May 29th. Because FDA is currently updating its website, the old links may no longer be active. The content of the guidance will be discussed in more detail on the June 15th call as needed.

IV. Highlights from FDA Face-2-Face Meeting

Highlights from the May 21st meeting were reviewed in addition to being provided as a separate document.

V. FDA Data Council

- A. The Data Council webpage was updated on May 29, 2009
<http://www.fda.gov/ForIndustry/DataStandards/default.htm>
- B. Guidance for Industry: Providing Regulatory Submissions in Electronic Format – Drug Establishment Registration and Drug Listing (Final)
<http://www.fda.gov/OHRMS/DOCKETS/98fr/2005-N-0464-gdl.pdf>
- C. Structured Product Labeling Implementation Guide for FDA Drug Establishment Registration and Drug Listing v2.0
http://www.fda.gov/oc/datacouncil/spl_r4_ig_v2_0.pdf
- D. Structured Product Labeling Validation Procedures for Drug Establishment Registration and Drug Listing v2.0
http://www.fda.gov/oc/datacouncil/SPL_r4_validation_procedures_v2_0.pdf
- E. Step-by-Step Instructions for Creating Structured Product Labeling (SPL) Files for Drug Establishment Registration and Drug Listing v2.0 -
http://www.fda.gov/oc/datacouncil/spl_r4_xforms_instructions_v2_0.pdf

VI. Open Discussion by Sub-team Members

- During the previous call (May 18th) there was an inquiry about what customer support services FDA might offer with the June 1st implementation date looming for OTC and Vet Med products? The concern was that both FDA and industry would be inundated with questions due to potential submission/transmission problems or lack of familiarity with the electronic submission process.

The FDA recently announced that it will be hosting weekly Q7A audio training sessions to respond to technical questions related to SPL. Details for the teleconferences are as follows.

Dates: Mondays, June 8, 2009 – December 28, 2009 (except June 22, 2009, and Federal holidays)

11:30 am – 12:00 pm ET

Telephone number: 1-866-775-9435

Participant pass code: 2219058

- Companies may experience difficulty accessing the Electronic Submission Gateway (EGS) due to high traffic. It was suggested that by leaving the mouse cursor at the same position (*i.e.*, don't move the mouse after you have clicked for access), it may speed up the connection.
- FDA has offered to hold SPL training sessions for individual companies if necessary. Please contact Lonnie Smith for more information (Lonnie.Smith@fda.hhs.gov).
- Craig Trautman (Intagras) informed sub-team members that the test version for SPL is different from the current product version. The Java folders and Cyclone files associated with the test version will need to be deleted. He also noted that during the transition from R3 to R4, you will not be able to see the documents because the schema is not available. Please contact Craig for more information (ctrautman@intagras.com).

VII. Upcoming SPL Educational Forums

A. FDA face-to-face meeting on June 10, 2009 (attendance will be limited to available seats)

B. FDA SPL R4 Training

1. Session 10, 11, and 12 (webinars)

Session 10 is no longer accepting registrations.

2. Sessions 13 and 14 (webinars) - NEW

June 19, 2009, 9:00 – 10:30 am ET

Bulk Ingredient/Bulk Product

Session 14: June 26, 2009, 9:00 – 10:30 am ET

OTC Drug Products

For more information or to register for any of the open sessions, please send an email to spl@fda.hhs.gov specifying the session/s for which you are interested.

C. DIA SPL Workshop (August 11-12, 2009, The Westin, Philadelphia, PA)

The registration brochure and agenda will be available soon.

[Now available at CHPA website: <http://www.chpa-info.org/meetings/StructuredProductLabelingMeeting.aspx>]